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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,313

06/30/2006

John Eldridge

PCFC-439-101 (PC64516)

8349

1473 7590 03/18/2011

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PATENT DOCKETING 39/361
1211 AVENUE OF THE AMERICAS
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EXAMINER

HIRIYANNA, KELAGINAMANE T

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

03/18/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPatentMail@ropesgray.com

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Office Action Summary	Application No. 10/550,313	Applicant(s) ELDRIDGE ET AL.	
	Examiner KELAGINAMANE HIRIYANNA	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-39, 46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-39, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/03/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/04/2010 has been entered.

Applicant's response filed on 08/04/2010 in response to office action mailed on 02/04/2010 has been acknowledged.

Claims 35-39, 46 and 47 are pending and presently under examination.

Claims 1-34 and 40-44 are withdrawn.

Claim 45 was previously canceled.

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is **571-273-8300**.*

Withdrawn: Claims 35, 37 and 38 rejection as failing to define the invention in the manner required by 35 U.S.C. 112, 2nd paragraph .for the reasons of record as set forth in the office action mailed on 06/24/2009 is withdrawn in view of Applicants amendments to cited claims.

Withdrawn: Claims 35-39, 46 and 47 rejection under 35 USC 103 (a) as being unpatentable over Ramshaw et al (2000, Trends Immunology Today 21:164-165; art of record) and Haglund et al (2002, J. Virol. 76:2730-2738; art of record) in view of Haglund, et al (2002, J. Virol. 76:7506-7507; art of record), and Gherardi et al (2000, J. Virol 74:6278-6286) for the reasons of record as set forth in the office action mailed on 02/04/2010 is withdrawn in favor of a new rejection below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35-39, 46 and 47 are rejected under 35 USC 103 (a) as being unpatentable over Ramshaw et al (2000, Trends Immunology Today 21:164-165; art of record) and Haglund et al (2002, J. Virol. 76:2730-2738; art of record) in view of Haglund_b et al (2002, J. Virol. 76:7506-7507; art of record), Gherardi et al (2000, J. Virol 74:6278-6286) and Barber et al (US20030044386 A1).

The above claims are drawn to an immunogenic composition to induce antigenic response in a mammalian subject wherein the composition comprises a DNA plasmid encoding an antigen expressed under the control of regulatory sequences and at least one recombinant vesicular stomatitis virus (VSV) vector comprising a nucleic acid sequence encoding said antigen directed by said recombinant VSV,

Ramshaw teaches using a prime-boost strategy with plasmids and viral vectors as an exiting prospect for improved vaccination (entire article; abstract). Ramshaw's prime boost vaccine in particular comprises DNA vaccines (plasmid vectors with antigen) as prime followed by boost with attenuated poxvirus vectors encoding the same antigens (entire article). Ramshaw however, does not teach using a VSV vector in their prime boost composition.

Regarding the claims Haglund teaches prime boost regimens comprising multiple vectors including VSV for inducing efficient antigenic response in mammals (entire article; abstract). Haglund teaches that prior art routinely uses prime-boost regimen using VSV vector as prime and a different strain of VSV encoding the same antigen as boost. Haglund clearly teaches that that the immune response elicited using VSV as vector was as high as six to eight fold higher than that could be obtained using a vaccinia virus vector indicating VSV is a preferred vector for vaccines over VV and safer than VSV based vaccine (entire article; abstract; p.2730, col.2) .

Regarding the claims Haglund_b teaches prime boost regimens comprising multiple vectors including VSV for inducing efficient antigenic response in mammals (entire article; abstract). Haglund_b teaches that prior art routinely uses prime-boost regimen using DNA plasmid expression vectors as prime and a viral vector encoding same antigen as boost (entire article; p.7507, col.1). Haglund_b clearly teaches that the immune response elicited using VSV as vector was as high as six to eight fold higher than that could be obtained using a vaccinia virus vector and further boosting with VV containing same antigen increased the efficacy. At the time of invention Haglund_b clearly establishes VSVs as the more efficient vectors than VVs and safer and Haglund clearly had established efficacy of VSVs for both priming and boosting.

Gherardi teaches regarding new generation of vaccines with cytokines as an adjuvant to enhance cellular immune responses to pathogens during prime-booster vaccination and further teaches the limitation of Interleukin-12 or (IL-2) as boost vaccine wherein a HIV Env (antigen) and IL-12 was used in plasmid vector during priming following a booster with vaccinia virus expressing said antigen and IL-12 was found to trigger optimal boost (entire article; abstract; p6278-6279). Gherardi's reference clearly teaches advantages of including IL-12 in the composition.

Barber teaches recombinant vesicular stomatitis virus vectors comprising nucleic acids encoding cytokines including IL-12 and can be both replication competent and replication deficient.

Thus it would have been obvious for one of ordinary skill in the art to modify Ramshaw's prime boost vaccine composition of an encoding plasmid vector prime & the same antigen in vaccinia virus vector as boost with the substitution of the more potent VSV vector encoding the same antigen as taught by Haglund & Haglund_b for the vaccinia virus of Ramshaw. to prepare a vaccine for inducing an antigen specific immune response in a mammal.. One of ordinary skill in the art would further add to said composition of composition an additional immune enhancing cytokine, specifically IL-12, as an expressible DNA sequence as taught by Gherardi for improving the efficacy of said prime boost composition. One of skill in the art would have been motivated to make and use said prime-boost strategy for efficaciously treating severe viral or pathogenic diseases.

One of ordinary skill in the art would have a reasonable expectation of success for making using said compositions because of the prior art clearly teaches prime boost strategy for an improved vaccination and prior art further clearly teaches improved prime boost and safety of using VSV over VV and further teaches using an immune enhancing cytokine IL-2 in the vaccination composition for increasing the efficacy of the same. Thus, the claimed invention was *prima facie* obvious.

Response to Applicants arguments in the reply of 08/04/2010:

The Applicant argues that the instant invention is not obvious because the art is unpredictable regarding using DNA-viral vector prime boost compositions and their success. Applicant further argues that results of Ramshaw reference are not entirely reproducible.

The Applicants arguments are however found, not persuasive because Ramshaw clearly teaches using DNA prime boost and judging from the positive reference to article in the art it is clear that in most cases the Ramshaw's DNA-prime boost technology is clearly reproducible. Further it is clear from the prior art including that of Ramshaw that the principle of prime boosting was very well established with various virus vectors used for boosting, although the VVs (pox viruses) and Modified Vaccinia-virus Ankara (MVA) are most frequently used at the time of invention. At the time of invention Haglund, further clearly establishes VSVs as the more efficient vectors than VVs and also safer. Haglund clearly had established efficacy of VSVs for both priming and boosting. Thus one of skill in the art would be clearly attracted to try VSV as a preferred vector along with a plasmid vector as a prime and thus making the instant invention obvious. Gherardi's reference clearly teaches advantages of including IL-12 in the composition and is included with reference to instant new claims. However to boost these results it is clear from the teachings of Barber that vesicular stomatitis viral vectors are readily available both as replication competent and as replication defective types and further they can be used for delivery of cytokines. The Applicant further should note that obviousness can only be

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established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." Hence the obviousness rejection of the instant invention is maintained with modifications as above.

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hirianna Ph.D.*, whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/ROBERT M KELLY/

Primary Examiner, Art Unit 1633